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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,765	12/17/2001	Derek Leigh Jones	10/009765	5113

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EXAMINER	
WITZ, JEAN C	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,765	JONES, DEREK LEIGH	
	Examiner	Art Unit	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-35* is/are pending in the application.

4a) Of the above claim(s) *17,26 and 29-33* is/are withdrawn from consideration.

5)☒ Claim(s) *1,3,5-16 and 18-23* is/are allowed.

6)☒ Claim(s) *24,25,27,28 and 34* is/are rejected.

7)☒ Claim(s) *35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed March 25, 2005 have been fully considered but they are not persuasive for the reasons with regard to the rejections set forth below.

Claim Identifiers

2. Applicants presented claim 29 in the listing of claims with the claim identifier "withdrawn – previously presented"; however, the claim was indicated as under consideration as a result of the previous amendment in the response to Applicants arguments to the restriction requirement and examined in the previous office action. In order to advance prosecution, this office action will continue to treat claim 29 as under consideration but Applicants are required in the response to this office action to present this claim (and all claims of record) with its appropriate and correct status identifier.

Election/Restrictions

3. Newly amended claim 26 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claim now no longer requires any limitation to the protein such as source or size and as a result is rendered an independent invention not requiring the same components as that of the elected invention and is not disclosed as capable of use together.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

prosecution on the merits. Accordingly, claim 26 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 1-11 are directed to an allowable product and process of making the product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 12-16 and 18-22, directed to process of making or using the patentable product and to product containing the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 12-16 and 18-22 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. In accordance with the Official Gazette notice, *supra*, claims 17, 26 and 29-33, which do not depend from or otherwise include all the limitations of the allowable product, have NOT been rejoined.

5. This application contains claims 17, 26 and 29-33 drawn to an invention nonelected with traverse in a paper received on July 26, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

Claims 24-25, 27-28 and 34 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a substance or mixture obtained by the process comprising heating fetal calf serum to a temperature between 60°C and 80°C for between 30 minutes and 12 hours, still does not reasonably provide enablement for claims to a "polymeric protein comprising a polymer of one or more proteins containing in fetal calf serum, having a molecular weight in excess of 2MDA

and having spheroid forming activity" or "a polymeric protein obtainable by heat treatment of fetal calf serum, whereby said polymeric protein is capable of spheroid forming activity". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the previous office action, the claims refer to a "polymeric protein comprising a polymer of one or more proteins containing in fetal calf serum, having a molecular weight in excess of 2MDA and having spheroid forming activity" and as "a polymeric protein obtainable by heat treatment of fetal calf serum, whereby said polymeric protein is capable of spheroid forming activity." However, the specification provides no further documentation as to the type and nature of the protein; in fact, the only true measure of success is defined not by the physical nature of the product but is instead measured by its activity. Fetal calf serum contains numerous proteins and the specification does not indicate how these proteins are polymerized, whether they are a homogeneous polymer or a heterogeneous polymer, or the required length of the polymer. Further, it remains unclear as to whether a single polymer is responsible for the activity or whether a mixture of polymers is required. Since fetal calf serum is normally used to promote attachment of cells to the culture vessel (see Blaauboer et al.), it remains unpredictable and therefore not enabled that one who would practice the invention could produce a polymerized protein from fetal calf serum and still have the reasonable expectation of success of obtaining spheroids in suspension in cell culture instead of attachment. The only way to provide this reasonable expectation of success

is to subject a starting material (fetal calf serum) to a process (heat treatment between 60°C and 80°C for between 30 minutes and 12 hours). Therefore, claims must be limited to the product of the practice of a specific process.

Applicants argue that "as long as the specification discloses at least one method for making and using the claimed invention, then the enablement requirement of 35 USC 112 is satisfied" citing In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) and that "Applicant believes that the specification discloses at least one method for making the claimed product. Indeed, as noted above, the Office Action even acknowledges that the present specification is enabling for a product obtained by the process." However, as stated in the rejection recited above, Applicants have provided evidence only that fetal calf serum that has been specifically treated, i.e. heat treatment between 60°C and 80°C for between 30 minutes and 12 hours, has the desired characteristic of forming spheroids. Applicants have provided no further characterization of the so-treated fetal calf serum or the individual components thereof other to state that the molecular weight of the protein polymer is in excess of 2Mda.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any

person skilled in the art can make and use the invention without undue experimentation. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In the instant application, the level of predictability in the production of spheroid inducing substances has been shown to be unpredictable insofar as the determination must be made based upon the successful production of a spheroid as evidenced by the limited relationship between the time and temperature used to produce the spheroid producing substance from fetal calf serum – too much or too little of either production parameter fails to produce spheroid forming substance. In the absence of a further showing definitively linking the appropriately treated starting material with a given

physical (versus functional) characteristic, claims to the substance merely by a physical characteristic would not allow one who would practice the claimed invention a reasonable expectation of success without engaging in undue trial-and-error experimentation. The practitioner would only have that reasonable expectation of success by engaging in the process as claimed to produce the appropriate product.

Allowable Subject Matter

6. Claims 1, 3, 5-16 and 18-23 are allowed.

7. Claim 35 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jean C. Witz
Primary Examiner
Art Unit 1651